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said volume swelling, and whereby horizontal swelling of said swelling composition is favored against vertical swelling.

20. (added claim) A method according to claim 19, wherein said swelling composition is covered by a cover selected from a group consisting of a plate, a film and a dressing.

REMARKS

Claims 1, 4, 5, 8, 9, 10, 12, and 19 have been amended to make clear the present invention over the prior art. Claim 20 has been added.

Claims 1, 2, 10, 11, 12, 14, 15 and 19 stand rejected under 3 U.S.C 102(b) as being anticipated by Suzuki et al., U.S. Patent No. 4,292,299.

In response to the examiners 102 (b) rejection of claims 1, 2, 10, 11, 12, 14, 15 and 19, the examiner is incorrect that the present invention was patented or described by Suzuki.

Suzuki et al. discloses a medical preparation composed of an adhesive layer comprising polymers having adhesiveness to a wet mucous surface and swellability upon moistening and a non-adhesive layer that is water-soluble or water disintegrable, with at least one of the layers made to contain a medicament. The preparation releases the medicament slowly over a long time. The Suzuki invention is aimed at the administration of the preparation fixed to the mucous membrane of the body cavity such as the oral cavity ('299 column 2, lines 19-21) or surfaces resulting from operation, cut or wound ('299 column 10, lines 60-68).

The present invention discloses methods for enhancing penetration of compounds/drugs into hair follicles. Skin surfaces containing hair follicles cannot be considered the same as the wet mucous surfaces described by Suzuki.

The swelling property of the Suzuki invention is necessary for the gradual release of the medicament. ('299 column 2, lines 38-42). There is no indication that the swelling polymer must be able to perform any other function.

A key aspect of the present invention is the application of a swellable composition which can maintain a passage for desired drugs by either opening hair follicles and preventing them from collapsing or increasing the depth of the inner lumen space of the hair follicles (specification, page 5, lines 23-26). Swelling may be induced by any known process (specification, page 9, line 9) not just moisture as taught in Suzuki. Swelling in the present invention must exert pressure on the hair follicle to prevent follicle collapse where a hair has been removed (specification, page 10, line 13) or exert forces at the inner lumen of the hair follicles to enlarge the space between the fourth and third hair follicle layers. (specification, page 12, lines 1-11).

The Suzuki patent requires a second, non-adhesive composition layer to accomplish the slow controlled release mechanism described. When the adhesive layer contains the medicament, the non-adhesive layer dissolves or disintegrates in the presence of bodily secretions to slowly expose the adhesive layer, which subsequently swells to release the medicament. When the non-adhesive layer contains the medicament, the layer gradually dissolves or disintegrates due to the body cavity secretions to slowly release the medicament. ('299, column 3, lines 29-42). A key aspect of the Suzuki invention is that the non-adhesive layer and the adhesive layer cooperate together to increase each other's efficiency ('299, column 4, lines 29-31).

The present invention does not require a second composition layer. A plate, film or dressing is preferentially applied above the composition layer during swelling to favor horizontal swelling against vertical swelling (specification, page 9 lines 16-18), but is not mandatory.

The Suzuki patent teaches the use of an adhesive layer in order to fix the preparation to the mucous membrane. ('299, column 2, lines 19-21).

The use of adhesives polymers with the present invention would prevent the compound from penetrating into the hair follicles, thereby hindering the enhancement of compounds/drugs into the follicle. This is contrary to the objects of the present invention.

The Suzuki '299 patent neither anticipates nor makes obvious the present invention.

Claims 2-5 and 9 stand rejected under 35 U.S.C 103 (a) as being unpatentable over Suzuki et al. (U.S. Patent No. 4,292,299) in view of Schaefer et al. (U.S. Patent No. 5,292,512).

Schaefer et al. teaches the use of a composition containing microspheres of polymers filled with an active product, characterized in that at least 80% of the microspheres have a diameter between 3 μm and 10 μm. An object of the '512 patent is to select the size of the microspheres so as to promote their selective entry into the sebaceous follicles ('512 column 2, lines 29-31). The general use of microspheres to contain an active substance is known in the state of the art ('512, column 1, lines 10-36).

The examiner cites that the microspheres taught by Schaefer et al. can be made by a polymer that swells, thereby creating the microsphere in gel form ('512 column 4, lines 65-67). Swelling is merely a method to produce the spheres. No swelling activity is described which takes place after the microsphere compound is applied to the skin. #1

The present invention uses composition swelling to force open the follicular space to permit increased flux of a compound/drug through the follicle to induce deeper penetration. (specification, page 10, lines 17-19).

Schaefer et al. also teaches using microspheres that can release active compounds selectively into sebaceous follicles. ('512, column 2, lines 29-31) It does not describe a method for enhancing penetration of compounds/drugs into hair follicles deeper than the sebaceous gland. Microspheres capable of swelling to force the hair follicle open are not disclosed. #2

Fig. 2A of the present invention illustrates the follicular collapse that occurs when a hair is removed or when there is no normal growing hair, such as alopecia (specification, page 10, lines 3-6). Without the exertion of the swelling forces taught in the present invention, the microspheres disclosed in Schaefer could not pass beyond the collapsed area. #3

For the Schaefer invention to work, the active ingredients must be added to the microspheres prior to application. The present invention, because of the permeability of the swelled composition, permits the topical application of compound/drugs solution. (specification, page 10, lines 15-17). As does Schaefer

The addition of Schaefer et al. to Suzuki et al. does not disclose nor make obvious the present invention as described in the specification and now claimed.

With these changes and remarks, it is believed that the disclosure is now in condition for allowance. Reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,

Dated: October 16, 2001

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MARK-UP CLAIMS

What is claimed is:

1. A method for enhancing compound/drug penetration into hair follicles on body areas of animals and [or] humans, comprising the steps of:

    a. applying topically a swellable composition to said body areas; [and]

    b. [volume swelling said composition applied in step a; and] allowing said composition to penetrate into said hair follicles; and

    c. volume swelling said swellable composition; wherein internal forces are generated by said swellable composition ing at said hair follicles during and after said volume swelling of said composition .

2. A method according to claim 1, wherein said swellable composition includes a compound/drug.

3. (Cancelled) [A method according to claim 1, wherein internal forces are generated at said hair follicles during and after said volume swelling of said composition.]

4. A method according to claim 1, wherein said swelling causes opening of said hair follicles and prevents said hair follicles from collapsing.

5. A method according to claim 1, wherein said swelling enlarges a depth of an inner lumen space of said hair follicles.

6. A method according to claim 1, wherein said method further comprising a pretreatment step of:

    removing hair from said hair follicles.

7. A method according to claim 1, wherein said method further comprising a pretreatment step of:

cutting external hairs.

8. A method according to claim 1, wherein said applying topically includes massaging said swellable composition into said body area having hair follicles.

9. A method according to claim 1, [wherein said method] further comprising another step after step [b] c: occluding said hair follicles.

10. A method according to claim 1, wherein said compounds/drugs are molecules [or] and their derivatives used in cosmetic[and/or] /pharmaceutic[s]al applications.

11. A method according to claim 1, wherein said compounds/drugs are photosensitizer molecules, their derivatives and their precursors used in photodynamic therapy.

12. A method according to claim 1, wherein said swellable composition is cosmetically[and/or] /pharmaceutically acceptable.

13. A method according to claim 1, wherein said swellable composition are polymers.

14. A method according to claim 13, wherein said polymers are biodegradable.

15. A method according to claim 13, wherein said polymers are biologically active.

16. A method according to claim 13, wherein said polymers are encapsulated.

17. A method according to claim 13, wherein said polymers are structures in a form of microspheres.

18. A method according to claim 13, wherein said polymers are encapsulated in liposomes.

19. A method according to claim 1, wherein said [a plate, a film, a dressing and the like are applied above said] swelling composition is covered during said volume swelling, and whereby horizontal swelling of said swelling composition is favored against vertical swelling.

20. (added claim) A method according to claim 19, wherein said swelling compositon is covered by a cover selected from a group consisting of a plate, a film and a dressing.

Abstract of the Invention

Methods for enhancing penetration of compounds/drugs into hair follicles of an animal or human are provided. The method employs topical application of swellable compositions which can maintain a passage for desired drugs by either opening hair follicles and preventing them from collapsing or increasing the depth of inner lumen space of the hair follicles. The swellable composition can be polymers that are biodegradable, bioactive, encapsulated in microspheres or liposomes, and/or form microspheres. The method is useful to increase compound/drug penetration deep into a hair follicle, to increase flux of compounds/drugs through the hair follicle, to obtain release of compounds/drugs in the tissues surrounding hair follicle or under the skin surface, and to obtain systemic effect of the compounds/drugs after topical application. The method is also useful to increase therapeutic effects of compounds/drugs in the treatment of a wide variety of skin disorders and more precisely, hair disorders in human, such as alopecia or hirsurtism. The method is further used to obtain temporary and/or permanent removing of unwanted hair by permitting the diffusion of compounds/drugs deeply into hair follicle.

What is claimed is:

1. A method for enhancing compound/drug penetration into hair follicles on body areas of animals and humans, comprising the steps of:

   a. applying topically a swellable composition to said body areas;

   b. allowing said composition to penetrate into said hair follicles; and

   c. volume swelling said swellable composition; wherein internal forces are generated by said swellable composition ing at said hair follicles during and after said volume swelling of said composition .

2. A method according to claim 1, wherein said swellable composition includes a compound/drug.

3. (Cancelled)

4. A method according to claim 1, wherein said swelling causes opening of said hair follicles and prevents said hair follicles from collapsing.

5. A method according to claim 1, wherein said swelling enlarges a depth of an inner lumen space of said hair follicles.

6. A method according to claim 1, wherein said method further comprising a pretreatment step of:

   removing hair from said hair follicles.

7. A method according to claim 1, wherein said method further comprising a pretreatment step of:

   cutting external hairs.

8. A method according to claim 1, wherein said applying topically includes massaging said swellable composition into said body area having hair follicles.

9. A method according to claim 1, further comprising another step after step c: occluding said hair follicles.

10. A method according to claim 1, wherein said compounds/drugs are molecules and their derivatives used in cosmetic/pharmaceutical applications.

11. A method according to claim 1, wherein said compounds/drugs are photosensitizer molecules, their derivatives and their precursors used in photodynamic therapy.

12. A method according to claim 1, wherein said swellable composition is cosmetically/pharmaceutically acceptable.

13. A method according to claim 1, wherein said swellable composition are polymers.

14. A method according to claim 13, wherein said polymers are biodegradable.

15. A method according to claim 13, wherein said polymers are biologically active.

16. A method according to claim 13, wherein said polymers are encapsulated.

17. A method according to claim 13, wherein said polymers are structures in a form of microspheres.

18. A method according to claim 13, wherein said polymers are encapsulated in liposomes.

19. A method according to claim 1, wherein said swelling composition is covered during said volume swelling, and whereby horizontal swelling of said swelling composition is favored against vertical swelling.

A5 cancel

20. (added claim) A method according to claim 19, wherein said swelling compositon is covered by a cover selected from a group consisting of a plate, a film and a dressing.